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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,504	12/17/2001	Ryszard Kobylecki	687-94	9353

7590

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EXAMINER

TRAN, MY CHAU T

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,504

Applicant(s)

KOBYLECKI, RYSZARD

Examiner

My-Chau T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-74 is/are pending in the application.
- 4a) Of the above claim(s) 59-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I (Claims 38-58) in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 59-74 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 38-58 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a written description rejection)

The instant claim 38 recites a method of synthesis using a porous device. The porous device comprises a body having an internal region which is porous, wherein an active material is entrapped within the internal region.

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The specification disclosure does not sufficiently teach the method of synthesis using a porous device (e.g. a synthesis of compounds such as biochemical compounds or organic compounds or a synthesis of making particles such as liposomes or hydrogel).

The specification description is directed to the porous device (pg. 3-10) and a method of using a porous device in an "assay" method (pg. 2, lines 14-33 to pg. 3, lines 1-4). This method clearly does not provide an adequate representation regarding method steps for any type of synthesis. The specification examples are drawn to methods of functionalizing resin (e.g. particle). The specification does not teach any method of synthesis using a porous device.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.).

With the exception of the method of functionalizing resin disclosed by the specification, the skilled artisan cannot envision the method of synthesis using a porous device (e.g. a synthesis of compounds such as oligonucleotide or peptidomimetic compounds or organic compounds or a synthesis of making particles such as liposomes or hydrogel). Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d

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1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

In the present instance, the method of the instant claims claimed a method of synthesis using a porous device. The specification does not teach the method of synthesis using a porous device (e.g. a synthesis of compounds such as biochemical compounds or organic compounds or a synthesis of making particles such as liposomes or hydrogel). Therefore, only the method of functionalizing resin, but not the full breadth of the claim method meet the written description provision of 35 U.S.C 112, first paragraph.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 38-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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- a) Clarification is needed for the terms of “material(s)”, “make(s)”, and “is/are” in claim 44.
- d) The term “predetermined” in claims 45 and 48 is a relative term, which renders the claim indefinite. The term “predetermined” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.
- f) Claim 46 does not further limit Claim 38; because internal region is defines in claim 38 as porous.

7. Claim 44 recites the limitation "material(s)" in line 1. There is insufficient antecedent basis for this limitation in claim 38.

8. Claims 53-54 recite the limitation "inert material" in line 1. There is insufficient antecedent basis for this limitation in the claim 38.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claims 38-56 and 58 are rejected under 35 U.S.C. 102(a) as being anticipated by BIOSEPRA INC. (WO 98/41534).

The instant claimed method of synthesis using a porous device. The porous device comprises an internal region, which is porous, and an active material, wherein an active material is entrapped within the internal region. The active material includes a linker. The method steps comprise contacting the porous device with a reagent, wherein the reagent is bonded to the active material and cleaving the compound from the active material.

BIOSEPRA INC. disclosed a method for solid phase synthesis of molecules using a porous ceramic solid support (porous device) (pg. 6, lines 7-16). The porous ceramic solid support comprises pore-filled ceramic particles (internal region) (pg. 6, lines 7-16; pg. 11, lines 17-25). The method steps comprise of derivatizing a three-dimensional polymer network within interior channels of the pore-filled ceramic particles with one or more appropriate chemical functionalities (active material), which permit attachment of an organic molecule (reagent) to the

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three-dimensional polymer network. The method step of subjecting the organic molecule to reactions, which result in synthesis of said molecules. The method step further comprise of coupling a compatible or appropriate linker to the functionality, coupling a first organic molecule such as amino acid or peptidomimetic moiety to the linker, and coupling one or more additional amino acid or peptidomimetic moiety to the first amino acid or peptidomimetic moiety. Then cleaving the resulting elongated polypeptide chain or peptidomimetic product from the porous ceramic solid support (pg. 6, lines 17-27; pg. 18, lines 15-20). Therefore, the method of BIOSEPRA INC. anticipates the presently claimed invention.

11. Claims 38, 42, 44, 46-48, and 50-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Rohrbach et al. (US Patent 4,218,363).

The instant claimed method of synthesis using a porous device. The porous device comprises an internal region, which is porous, and an active material, wherein an active material is entrapped within the internal region. The method step comprises contacting the porous device with a reagent, wherein the reagent is bonded to the active material.

Rohrbach et al. disclosed a process for preparing support matrices for immobilized enzymes (Abstract; col. 6, lines 23-35). The matrices (porous device) comprise a combined organic-inorganic material. The inorganic materials (internal region) consist of a porous support material, which entrapped in the pores organic material (active material) (col. 9, lines 50-67). The organic material contains terminally positioned functional moiety that covalently bond to the enzymes (reagents) (col. 10, lines 3-25). Therefore, the method of Rohrbach et al. anticipates the presently claimed invention.

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12. Claims 38-58 are rejected under 35 U.S.C. 102(e) as being anticipated by Kobylecki et al. (US Patent 6,153,375; filing date of 5/16/1997).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The instant claimed method of synthesis using a porous device. The porous device comprises an internal region, which is porous, and an active material, wherein an active material is entrapped within the internal region. The method steps comprise contacting the porous device with a reagent, wherein the reagent is bonded to the active material and cleaving the compound from the active material.

Kobylecki et al. disclosed a method of making a library of compounds (col. 2, lines 60-67 to col. 3, lines 1-19; claim 12). The method comprise of providing a solid support material (porous device) to which compounds (reagents) maybe releasably bound. The solid support material comprises a layer of a particulate, functionalized solid support resin (active material) affixed to a porous, inert, laminar material (claim 12; col. 4, lines 22-33; col. 4, lines 44-48). The compounds prepared in the library may be linked to the support by a wide variety of methods (col. 5, lines 7-8). The method further comprise of cleaving the compound from the

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support (col. 7, lines 6-14). Therefore, the method of Kobylecki et al. anticipates the presently claimed invention.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on ***Increased Flex Schedule*** and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
April 7, 2003


ANDREW WANG
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